EXAMPLE 23

In the chemical stability test program Form K batch 1 was stored for a period of 1 and 4 weeks under different conditions. These conditions were 40° C./75% RH, 50° C., RT/75% RH and 0.3da ICH light. Form K batch 2 was also stored for a period of 1 and 4 weeks under different conditions. These conditions were 40° C./75% RH, 50° C., RT/<5% RH, RT/56% RH, RT/75% RH and 0.3 da ICH light. The compound was analysed after storage by HPLC and by visual inspection. The HPLC method used in this study was HPLC method 909. The results of the tests are reported in the following table.

TABLE 26

		HPLC Sum of impurities		appearance	
compound	conditions	1 week	4 weeks	1 week	4 weeks
Form K batch 1	Reference	3.57	—	slightly-orange	—
	0.3 da ICH light	2.93	—	slightly-orange	—
	40° C./75% RH	5.36	>90*	slightly-orange	brown oil
	50° C.	3.99	27.53	slightly-orange	orange
	RT/75% RH	—	3.61	—	slightly-orange
Form K Batch 2	Reference	1.50	—	slightly-orange	—
	0.3 da ICH light	1.17	—	slightly-orange	—
	40° C./75% RH	1.75	>85*	slightly-orange	brown oil
	50° C.	1.46	1.25	slightly-orange	slightly-orange
	RT/<5% RH	—	1.58	—	slightly-orange
	RT/56% RH	—	1.45	—	slightly-orange
	RT/75% RH	—	1.46	—	slightly-orange

EXAMPLE 24

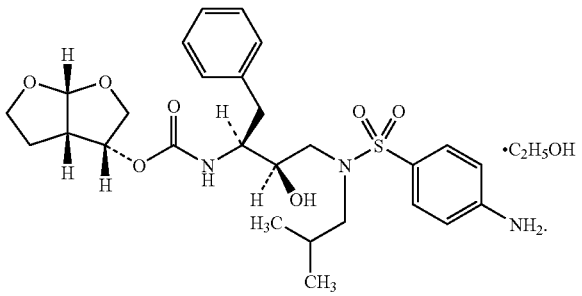
A randomized, placebo-controlled, double-blind, multiple dose escalation trial was performed to examine the safety, tolerability and pharmacokinetics of Form A after oral administration twice or three times daily, in healthy subjects. Four dosages of Form A (400 mg b.i.d., 800 mg b.i.d., 800 mg t.i.d., and 1200 mg t.i.d.) were tested in 4 panels of 9 healthy subjects. Within each panel, 6 subjects were treated with Form A and 3 subjects with placebo for 13 days with a single intake in the morning of day 14. (b.i.d.=twice daily, t.i.d.=three times daily).

Form A was readily absorbed and concentration-time profiles of Form A after repeated dosing were dependent on the dose administered. Steady-state plasma concentrations were reached generally within 3 days, although C_{0h} (conc. at administration time) and AUC_{24h} (area under de curve or bioavailability) slightly decreased over time at all dose levels. AUC_{24h} and $C_{ss,av}$ (conc. at average steady-state) were dose-proportional (daily dose) at 400 mg b.i.d., 800 mg t.i.d. and 1200 mg t.i.d., but was more than dose-proportional at 800 mg b.i.d. C_{max} (maximum conc.) was dose-proportional with respect to dose per intake. Less than 2% of unchanged Form A was excreted in the urine at all dose levels.

The invention claimed is:

1. An ethanolate solvate of the compound (3R,3aS,6aR)-hexahydrofuro[2,3-b]furan-3-yl(1S,2R)-3-[[(4-aminophenyl)sulfonyl](isobutyl)amino]-1-benzyl-2-hydroxypropylcarbamate, in which the ratio of compound to ethanol is about 1:1.

2. A solvate having the formula:

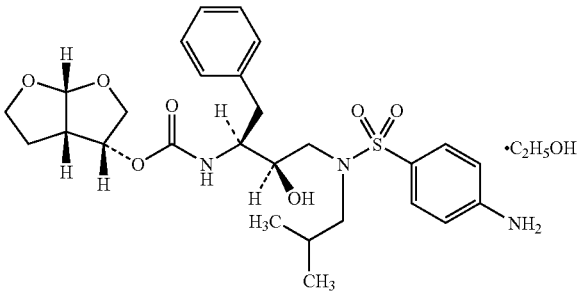


3. A composition comprising an ethanolate solvate of the compound (3R,3aS,6aR)-hexahydrofuro[2,3-b]furan-3-yl (1S,2R)-3-[[(4-aminophenyl)sulfonyl](isobutyl)amino]-1-benzyl-2-hydroxypropylcarbamate, in which the ratio of compound to ethanol is about 1:1, and an inert carrier.

4. The composition of claim **3** wherein the inert carrier is a pharmaceutically acceptable carrier.

5. The composition of claim **4** wherein the pharmaceutically acceptable carrier is a solid inert carrier.

6. A composition comprising a solvate having the formula:



and an inert carrier.

7. The composition of claim **6** wherein the inert carrier is a pharmaceutically acceptable earner.

8. The composition of claim **7** wherein the pharmaceutically acceptable carrier is a solid inert carrier.

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